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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,889	02/11/2004	Anthony J. Kinney	BB1531 US NA	3661

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EXAMINER	
KUMAR, VINOD	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,889	KINNEY ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *3 and 4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/23/04, 1/10/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 5 and 6-13, drawn to an isolated nucleic acid fragment comprising a seed-specific soybean annexin promoter as set forth in SEQ ID NO: 1 or deletion fragments thereof as set forth in SEQ ID NOs: 13-22, or a recombinant expression construct comprising at least one heterologous nucleic acid fragment operatively linked to said promoter, or wherein the heterologous nucleic acid fragment encodes an enzyme related to production of at least one long chain polyunsaturated fatty acid, or a method of regulating expression of heterologous nucleotide sequence in plant comprising transforming plant cell with said expression construct and producing fertile mature transgenic plants from transformed plant cell expressing said heterologous polynucleotide sequence encoding an enzyme related to production of at least one long chain fatty acid, or wherein the said transgenic plant is selected from the group consisting of dicotyledonous plants like soybean, classified in class 800, subclass 289, for example.

II Claims 3, 4, 5 and 6-13, drawn to an isolated nucleic acid fragment comprising a seed-specific P34 soybean promoter, or wherein said promoter consists essentially of the nucleotide sequence set forth in SEQ

ID NO: 2, or a recombinant expression construct comprising at least one heterologous nucleic acid fragment operatively linked to said promoters, or wherein the heterologous nucleic acid fragment encodes an enzyme related to production of atleast one long chain polyunsaturated fatty acid, or a method of regulating expression of heterologous nucleotide sequence in plant comprising transforming plant cell with said expression construct and producing fertile mature transgenic plants from transformed plant cell expressing said heterologous polynucleotide sequence encoding its polypeptide, or wherein the said transgenic plant is selected from the group consisting of dicotyledonous plants like soybean, classified in class 800, subclass 289, for example.

Inventions I and II are patentably distinct. The nucleotide sequence set forth in Group I is a seed specific annexin promoter that participates in cell division during early seed developmental stages preceding reserve deposition. Their turnover during seed development reflect switch from embryogenesis to seed filing. The nucleotide sequence set forth in Group II is also a seed-specific promoter but with different expression pattern during the development of seed. P34 promoter is active during reserve deposition whereas annexin is active preceding reserve deposition, and the two promoters play entirely distinct role during soybean seed development.

Furthermore, the promoter of Group I would require different literature search strategy compared promoter of Group II. The technical literature search for Groups I and II is not coextensive and can impose search burden.

For each of the inventions above, restriction to one of the following is required under 35 USC 121. **Applicants are also required to elect** one nucleic acid sequence and one encoded amino acid sequence to be examined in conjunction with the elected group of claims. In the present case the restriction grouping is primarily based on two different polynucleotide promoter sequences set forth in SEQ ID NOs : 1 and 2, therefore election is required for one of the inventions I-II. For the Group I, SEQ ID NO: 1 with any 9 deletion fragments of SEQ ID NO: 1 set forth in SEQ ID NOs: 13-22, and Group II with its SEQ ID NO: 2. This requirement is not to be construed as a requirement for an election of species, since each nucleotide sequence is not a member of single genus of invention, but constitutes an independent and patentably distinct invention.

During a telephone conversation with Jonathan Narita on August 22, 2005 a provisional election was made without traverse to prosecute the invention of Group I with SEQ ID NOs. 1, 13-21. Affirmation of this election must be made by applicant in replying to this Office action. SEQ ID NOs: 2 and 22, and claims 3 and 4 directed towards SEQ ID NO: 2, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

2. The abstract of disclosure is objected to because of the following informalities: Abstract should be within the range of 50-250 words. It should also reflect the claimed invention.

Appropriate correction is required.

Claim Objections

3. Claims 5-13 are objected for depending from non-elected claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 5-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method for regulating expression of at least one heterologous nucleotide sequence in soybean seed, wherein the method comprises transforming a plant cell with the recombinant expression construct comprising an isolated nucleic acid fragment comprising a seed-specific soybean annexin promoter set forth in SEQ ID NO: 1 or its deletion fragment set forth in SEQ ID NOs: 13-21, operably linked to the heterologous nucleotide sequence, growing fertile mature plants from transformed plant cell and selecting transgenic plants comprising a transformed plant

cell expressing the heterologous nucleotide sequence during seed development, does not reasonably provide enablement in the claimed method using said construct in tissues other than seed. The specification also does reasonably provide enablement in the claimed transgenic plant or method of regulating expression of at least one heterologous nucleotide sequence in a transgenic plant comprising an expression construct comprising annexin promoter other than defined in SEQ ID NO: 1 or its deletion fragment as set forth in SEQ ID NOS: 13-21. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the method claimed in the invention commensurate in scope with these claims.

The claims are broadly drawn to an isolated nucleic acid fragment comprising a seed-specific soybean annexin promoter, a recombinant expression construct comprising at least one heterologous nucleic acid fragment operably linked to annexin promoter or a method for regulating expression of at least one heterologous nucleotide sequence in plant comprising transforming a plant cell with the recombinant expression construct comprising soybean annexin promoter nucleotide sequence set forth in SEQ ID NO: 1 or its deletion fragment set forth in SEQ ID NOs: 13-21, growing fertile mature plants from transformed cell and selecting transgenic plants comprising a transformed plant cell expressing heterologous nucleotide sequence, or wherein the transgenic plant is soybean, or wherein the heterologous nucleic acid fragment encodes an enzyme related to production of at least one long chain polyunsaturated fatty acid.

The specification teaches a strong seed-specific annexin promoter as defined in SEQ ID NO: 1 or its deletion fragments as set forth in SEQ ID NOs: 13-21 that drive high level expression of the heterologous nucleotide sequence encoding a reporter protein in seeds without producing detectable expression in other tissues. See page 14 and lines 10-15 of specification.

Claim 1 and claims dependent therefrom encompass all seed-specific soybean annexin promoters that may have different regulatory roles during seed development. Specification teaches the regulatory role of a annexin promoter as defined in SEQ ID NO: 1 and its deletion fragments as set forth in SEQ ID NOs: 13-21. But the specification does not teach other members of annexin promoter family that are regulated in seed-specific manner in soybean seed.

It is well established in art that all seed-specific promoters in a gene family do not necessarily participate in regulating gene expression at the same stage of seed development. Some members switch on early while as others become active at mid or late stages of embryo and seed development. For example, members of oleosin seed-specific promoter family of soybean participate in seed development at different stages of embryogenesis and oil synthesis. Thus undue experimentation by a skilled artisan will be required to make use of all such annexin seed-specific promoters of soybean that are not taught in present invention, in a method to produce transgenic soybean seed comprising regulating expression of the heterologous nucleic acid fragment that encodes an enzyme related to production of at least one long chain polyunsaturated fatty acid.

Furthermore, the specification does not teach the method comprising regulating expression of heterologous nucleotide sequence encoding an enzyme related to production of at least one long chain polyunsaturated fatty acid in plant tissues other than seed using annexin promoter of SEQ ID NO: 1 or deletion fragments thereof set forth in SEQ ID NOs 13-21. The specification teaches the use of an isolated nucleic acid comprising a nucleotide sequence set forth in SEQ ID NOs: 1 (soybean annexin promoter) or its deletion fragments set forth in SEQ ID NOs: 13-21 in driving expression of an heterologous nucleic acid fragment encoding GUS protein in transgenic soybean seeds. See page 20, last paragraph; Figures 1 and 6 of specification. But it is well established that seed specific promoters comprise conserved nucleotide sequences that direct strong seed-specific expression of storage proteins in only seeds. These conserved nucleotide sequences respond to a variety of plant transcription factors that are expressed only in seed tissue. For example, the genes that are specifically expressed in seeds are regulated by a number of seed specific regulators like PvALF which transactivates the promoters of genes expressed specifically in seeds. Pv ALF, VP1 etc., are transcription factors that are expressed in seed-specific manner and are required to modulate expression of genes in seed-specific manner. See Bobb et al. (Nucleic Acids Research, 25:641-647, 1997), page 1, Abstract; page 643; page 646-647, discussion part. In the absence of such transcription factors in tissues other than seeds, it will be highly unpredictable for annexin promoter from soybean to drive the expression of the heterologous DNA sequence in tissues other than seed because the necessary components required for its regulation would be unavailable in such non-

seed tissue to produce a transcript from the heterologous DNA. Besides the Applicants in the instant case acknowledge the tight seed-specificity of annexin promoter as recited in the specification " A strong seed-specific annexin or P34 promoter will produce high expression of reporter in the seeds without detectable expression in other plant tissues" See page 14, lines 13-15 of specification.

Based on the prior art and the description outlined in the specification about the tight seed specificity of annexin seed specific promoter or deletion fragments thereof, it will be highly unpredictable to use the method for regulating expression of at least one heterologous nucleotide sequence encoding an enzyme related to production of long chain polyunsaturated fatty acid in tissues other than seed. In the absence of further guidance through working example or disclosure in the specification that annexin seed specific promoter can drive the expression of an heterologous nucleotide sequence encoding an enzyme related to production of at least one long chain polyunsaturated fatty acid in plant transgenic tissues other than seed, undue experimentation would be required by one skilled in art to use the method for regulating expression of at least one heterologous nucleotide sequence encoding an enzyme related to production of at least one long chain polyunsaturated fatty acid in tissues other than seed.

Given the breadth of the claims encompassing all seed-specific soybean annexin promoter or method for regulating expression in plant comprising at least one heterologous nucleotide sequence in plant transformed with a recombinant construct comprising annexin promoter or deletion fragments thereof operably linked with a heterologous nucleotide sequence that encodes an enzyme related to production of at

least one long chain polyunsaturated fatty acid, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use of claimed invention. Therefore, it is maintained that the claims are not commensurate in scope with the teachings of the specification.

5. Claims 1 and 5-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to an isolated nucleic acid fragment comprising a seed-specific soybean annexin promoter, a recombinant expression construct comprising at least one heterologous nucleic acid fragment operably linked to annexin promoter or a method for regulating expression of at least one heterologous nucleotide sequence in plant comprising transforming a plant cell with the recombinant expression construct comprising soybean annexin promoter nucleotide sequence set forth in SEQ ID NO: 1 or its deletion fragment set forth in SEQ ID NOs: 13-21, growing fertile mature plants from transformed cell and selecting transgenic plants comprising a transformed plant cell expressing heterologous nucleotide sequence, or wherein the transgenic plant is soybean, or wherein the heterologous nucleic acid fragment encodes an enzyme related to production of at least one long chain polyunsaturated fatty acid.

The specification describe a strong seed-specific annexin promoter as defined in SEQ ID NO: 1 or its deletion fragments as defined in SEQ ID NOs: 13-21 that produce expression of a heterologous nucleotide sequence encoding a reporter protein in transgenic soybean seeds. See page 14 and lines 10-15 of specification.

Claim 1 encompasses any seed-specific soybean annexin promoter that can drive the expression of a heterologous nucleotide sequence in a seed-specific manner. Annexins can be diverse, multigene protein family in a single plant species. For example, at least seven annexin homologs have been identified in *Arabidopsis*. See Clark et al. (Plant Physiol., 126:1072-1084, 2001), Page 1074, Figure 1; Page 1075, Figure 3. There could be other seed-specific annexin promoters of soybean that display developmentally regulated tissue-specific and cell specific expression patterns that are different than the annexin promoter as defined in SEQ ID NO: 1 or its deletion fragments as defined in SEQ ID NOs: 13-21. The specification does not describe seed-specific annexin promoters of soybean that are not 100% identical to SEQ ID NO: 1 or its deletion fragments as defined in SEQ ID NOs: 13-21. The specification also does not describe a method of regulating expression of a heterologous nucleotide sequence encoding an enzyme related to production of at least one long chain polyunsaturated fatty acid using seed-specific annexin promoter(s) that are not 100% identical to SEQ ID NO: 1 or its deletion fragments as defined in SEQ ID NOs: 13-22. The specification does not teach structures of all other possible species with identical function as encompassed by the claim 1 and claims dependent therefrom. The specification does not describe functional domains of all such possible structures. The only species

described are the polynucleotide sequences set forth in SEQ ID NO: 1 or its deletion fragments set forth in SEQ ID NOs: 13-21. Thus it is quite clear that the invention encompassed in claim 1 and claims dependent therefrom was never reduced to practice as Applicants fail to disclose that all said structures and correlate them with the function of expressing a heterologous gene in soybean seed in a seed-specific manner.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

5. *Conclusion*

SEQ ID NO: 1 and 13-21 are free from prior art. Claim 2 will be allowed after Applicant amend claim 2 to delete non-elected SEQ ID NO: 22.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, William (Gary) Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300. Information regarding the status of an application may be obtained from the

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